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(72)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/297,040 07/21/99 MOSE LARSEN

P 0785.0390004

HM12/1004  
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EXAMINER

KAUSHAL, S

ART UNIT

PAPER NUMBER

1633

DATE MAILED:

10/04/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/297,040

Applicant(s)  
Larsen et al

Examiner  
SUMESH KAUSHAL

Group Art Unit  
1633



- ☐ Responsive to communication(s) filed on \_\_\_\_\_
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

- ☒ Claim(s) 1-27 \_\_\_\_\_ is/are pending in the application.
- Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☒ Claims 1-27 \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- ☐ Notice of References Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

# Restriction Election

Date Contacted \_\_\_\_\_

App. Ser. No. \_\_\_\_\_

Attorney Docket # \_\_\_\_\_

Attorney Name \_\_\_\_\_

Attorney Phone # \_\_\_\_\_

Elected Group \_\_\_\_\_

WITH Traverse

WITHOUT Traverse

146

12,13

Group #	Claims	Invention
I	1-6,	in vivo method identifying diabetes modulating Protein
II	7-11	Diabetes modulating protein
III	14-	in vitro method of identifying diabetes modulating protein
IV	15-18	Tg animal, & use
V	19, 24, 25, (26)	method; therapy; diabetes antiserum
VI	19, 24, 25, (26)	antibody
VII	19, 24, 25, (22-23)	Protein.
VIII	19, 24, 25, (26)	DNA
IX	27	method identify compound.

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Art Unit: 1633

***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-6, drawn to an in vivo method for identifying a diabetes-mediating protein.

Group II, claim(s) 7-11, drawn to a diabetes mediating protein.

Group III, claim(s) 14, drawn to an in vitro method of identifying a protective or deleterious diabetes mediating protein.

Group IV, claim(s) 15-18, drawn to a transgenic non-human mammal and its use.

Group V, claim(s) 19, 20, 24, 25, drawn to method of treating or preventing diabetes using an antisense sequence.

Group VI, claim(s) 19, 21, 24, 25, drawn to method of treating or preventing diabetes using an antibody.

Art Unit: 1633

Group VII, claim(s) 19, 22-25, drawn to method of treating or preventing diabetes using a protein.

Group VIII, claim(s) 19, 24, 25, 26, drawn to method of treating or preventing diabetes using polynucleotide.

Group IX, claim(s) 27, drawn to a method of identifying a compound capable of modulating the activity of a diabetes-mediating protein.

2. The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: 1) A product and a process specially adapted for the manufacture of said product; or 2) A product and a process of use of said product; or 3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or the said product; or 4) A process and an apparatus or means specifically designed for carrying out the said process; or 5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process (MPEP 37 CFR 1.475 (b)).

The special technical feature of group-I is the identification of a diabetes mediating protein in vivo which requires the transplantation and removal of insulin secreting cells. The special technical feature of group-II is a diabetes mediating protein. The special technical feature of group-III is the

Art Unit: 1633

identification of a protective or deleterious diabetes mediating protein in vitro wherein the cells are transfected with a nucleic acid sequence encoding a diabetes mediating protein. The special technical feature of group-IV is a transgenic non-human mammal and the method of using the same. The special technical feature of group-V is a method of treating or preventing diabetes or diabetes related disorders by administering an antisense sequence. The special technical feature of group-VI is a method of treating or preventing diabetes or diabetes related disorders by administering an antibody. The special technical feature of group-VII is a method of treating or preventing diabetes or diabetes related disorders by administering a diabetes mediating protein. The special technical feature of group-V is a method of treating or preventing diabetes or diabetes related disorders by administering a polynucleotide.

Proteins, nucleic acid and antibody are structurally and functionally different compounds with different uses. Therefore, a method of treating or preventing diabetes or diabetes related disorders by administering these products are technically distinct. Furthermore, the method of identifying diabetes mediating protein is technically distinct from the transgenic non-human animal because these invention have different modes of operation, functions and effects. Thus, these inventions are technically distinct and separate uses.

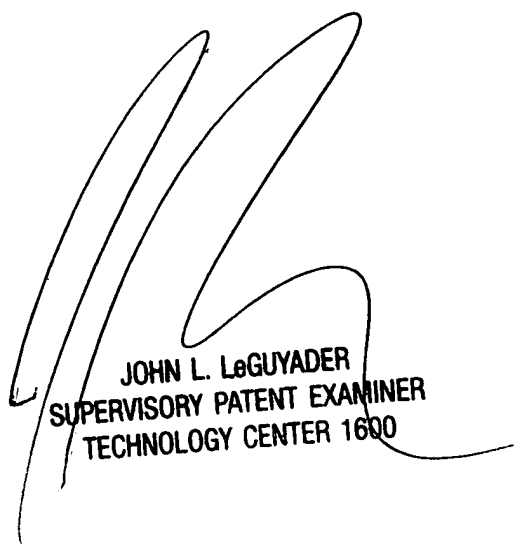
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Art Unit: 1633

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is (703) 305-6838. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor John L. LeGuyader can be reached on (703) 308-0447. The fax phone number for the organization where this application or proceeding is assigned as (703) 308-2035. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703) 308-0196.

S. Kaushal, AU 1633



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